K093914

APR 14 2011

510(k) SUMMARY

Modified Newdeal® Compression Plates

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Date Summary was prepared:

March 14, 2011

K093914

Name of the device:

Proprietary Name:	Newdeal Compression Plates
Common Name:	Plate, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (21CFR 888.3030)
Device Product Code:	HRS
Classification Panel:	Orthopedic

Substantial Equivalence:
The modified Newdeal Compression Plates are substantially equivalent to the commercially marketed device, Newdeal Compression Plates, K070447, cleared on March 29, 2007.

Device Description:
The Newdeal Compression Plates will offer the combination of two concepts:

- By widening the "eye" (diamond shaped opening) on the interaxis of the plate, mechanical deformation leads to narrowing of the interaxis of the two legs and thus provides compression between the two bone fragments to fuse.
- The rigidity of the "legs" is obtained using the Newdeal Locking System including a screw and a washer.

Indications for Use:
The **Newdeal Compression Plates** are intended for fixation of bone fractures or for bone reconstruction.

Examples include:

- Arthrodesis in hand or foot surgery
- Fracture management in the foot or hand
- Mono or Bi-cortical osteotomies in the foot or hand
- Distal or proximal metatarsal or metacarpal osteotomies
- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc)

The Newdeal Uni-CP™ U-Plate is intended for arthrodesis of the second and third cuneo-metatarsal and the inter-cuneiform second and third joints.

The size and number of the plate(s) used should be adapted to the specific indication.

Testing and Test Results:
Static and dynamic 4-point bending mechanical tests have been carried out. Results have shown that the mechanical properties of the modified Newdeal Compression Plates are substantially equivalent to the properties of the predicate devices: unmodified Newdeal Compression Plates, K070447, cleared on March 29, 2007.

Conclusion
The modified Newdeal Compression Plates are substantially equivalent to the commercially marketed devices, unmodified Newdeal Compression Plates (K070447).

The proposed device does not change the intended use or fundamental scientific technology of the predicate device, and does not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Newdeal SAS
% Integra LifeSciences Corporation
Mr. Frederic Testa
Director of Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey

APR 14 2011

Re: K093914
Trade/Device Name: Newdeal® Compression Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: April 11, 2011
Received: April 12, 2011

Dear Mr. Testa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): N/A K093914

Device Name: Newdeal Compression Plates

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Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Mallerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093914